nutrients by means of a testing program designed to confirm uniformity of batches and to determine the effects of such changes. The following shall apply:

(1) A minor change is a minor reduction in nutrient levels, a minor increase in levels of nutrients that are subject to maximum limits established under section 412(g) of the act or in regulations established under section 412(a)(2) of the act, or any other change where experience or theory would not predict a possible significant adverse impact on nutrient levels or nutrient availability. After a minor change the manufacturer shall analyze representative samples for all nutrients so changed and those possibly affected by the change.

(2) A major change is any new formulation, or any change of ingredients or processes where experience or theory would predict a possible significant adverse impact on levels of nutrients or availability of nutrients. After a major change the manufacturer shall analyze representative samples for osmolality, all nutrients, and the biological quality of the protein. A protein biological quality analysis is not necessary for a formulation change that is not expected to have an adverse effect on the biological quality of the protein. Vitamin D shall be determined by the rat bioassay method as prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists'' (AOAC), 13th Ed. (1980), sections 43.195–43.208, ''Vitamin D (30)—Official Final Action,'' which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*Before release of the product for commercial or charitable distribution, the manufacturer shall have completed all appropriate analyses except that shipment of the product need not be delayed until results of the vitamin D bioassay and, if required, a protein biological quality bioassay are complete, provided such bioassays have been initiated, and if another analysis for the vitamin D has been run and the protein content has been determined by a suitable method. The biological quality of the protein shall be determined by an appropriate modification of the AOAC bioassay method of analysis. The manufacturer shall analyze additional samples from the same batch for vitamin D, by any suitable method, and for the biological quality of the protein. The manufacturer shall perform such analyses at least annually for a period not to exceed the expected shelf life of the product.

(d) A simple adjustment in the level of an ingredient to accommodate inconsistencies in processing is considered to be neither a minor nor a major change.

[47 FR 17025, Apr. 20, 1982, as amended at 54 FR 24891, June 12, 1989; 63 FR 14035, Mar. 24, 1998]

§ 106.90 Coding.

The manufacturer shall code all infant formulas in conformity with the coding requirements that are applicable to thermally processed low-acid foods packaged in hermetically sealed containers as prescribed in § 113.60(c).

Subpart C—Records and Reports

§ 106.100 Records.

(a) Every manufacturer of infant formula shall maintain the records specified in this regulation in order to permit the Food and Drug Administration to determine whether each manufacturer is in compliance with section 412 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) The manufacturer shall maintain all records that pertain to food-packaging materials subject to § 174.5 of this chapter and that bear on whether such materials would cause an infant formula to be adulterated within the meaning of section 402(a)(2)(C) of the act.

(c) The manufacturer shall maintain all records that pertain to nutrient